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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/183,972	10/29/1998	GREGORY S. HAGEMAN	UIA-027.01	3707

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EXAMINER
TURNER, SHARON L

ART UNIT	PAPER NUMBER
1647	26

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/183,972	Hageman
Examiner	**Art Unit**
Sharon L. Turner, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 11-28-01

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4-13, 23-27, and 31-55 is/are pending in the applica

4a) Of the above, claim(s) 1, 4-13, 23-27, and 31-45 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 2 and 46-55 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1, 2, 4-13, 23-27, and 31-55 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-28-01 has been entered.

2. The amendment filed 11-28-01 has been entered into the record and has been fully considered.

3. Claims 1-2, 4-13, 23-27, and 31-55 are pending.

Election/Restriction

4. As set forth in Paper No. 20, mailed 5-15-01, newly submitted claims 1, and 33-45 were directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants originally election invention was drawn to nucleic acids of SEQ ID Nos:1, 3 and 5 and sequences hybridizing thereto. Applicants amended claims are now drawn to following patentably distinct inventions: I. Nucleic acids encoding 72 contiguous amino acids of SEQ ID NO:6, II. Nucleic acids encoding 180 contiguous amino acids of SEQ ID NO:4, III. Nucleic acids encoding 10 contiguous amino acids of SEQ ID NO:2, IV. Nucleic acids encoding 10 contiguous amino acids of residues 42-215 of SEQ ID NO:4, V. Nucleic acids encoding 136 contiguous amino acids of residues of 221-565 of SEQ ID NO: 4, VI. Nucleic

acids encoding 20 contiguous amino acids of residues 591-630 of SEQ ID NO:4, VII. Nucleic acids encoding 10 contiguous amino acids of residues 688-731 of SEQ ID NO:4, VIII. Nucleic acids encoding 5 contiguous amino acids of residues 735-743 of SEQ ID NO:4 and IX. Nucleic acids encoding residues 42-215, 221-565, 591-630, 688-731 (and 735-743) of SEQ ID NO:4. A complete search of the prior art for the nucleic acids of Groups I-IX will not reveal whether any prior art exists as to the other Groups. A search is directed to references which would render the invention obvious, as well as to references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. Further, the claimed nucleic acids are patentably distinct because the nucleic acids represent unique structures which are not shared and are capable of distinct functions and uses.

Although the classifications for these various nucleic acids overlap, for instance 536/23.1, each represents a patentably distinct product with distinct physical and functional characteristics, alternatively classified in for example 536/23.5, 536/24.31, and 24.33. Further the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, requires a search of the corresponding regions, reverse translations and oligomers contained therein for each representative SEQ ID NO. Thus, each individual sequence may require multiple sequence searches not required for any other sequence, to reveal prior art. Accordingly, restriction is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 and 33-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Applicant's traverse the restriction requirement of claims 1 and 33-45 set forth in the action of 5-15-01, Paper No. 20, reiterated above. The traversal is on the ground(s) that the claims are directed to closely-related subject matter and that the subject matter of claims 1 and 33-45 are not necessarily patentable over the other pending claims. Applicant's submit that there is no burden on the examiner as the subject matter is similarly classified and that the search already performed would reasonably encompass the same subject matter. This is not found persuasive because as previously set forth the claimed subject matter is directed to distinct molecules because the sequences lack a common core structure and are capable of different functions and alternative use, the searches are not co-extensive, and the multiple searches previously performed for SEQ ID NO's:1, 3 and 5 would not be co-extensive or reveal all relevant art for example to the alternative sequences of contiguous segments of SEQ ID NO's 2, 4 and 6.

The requirement is still deemed proper and is therefore made FINAL.

6. Claims 1, 4-13, 23-27, and 31-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15 and 25.

7. It is noted that the status of the claims as indicated above differs from that of Applicant's Remarks. There is no record of cancellation of claims 1, 4-13, 23-27, 31-32 and 33-45. Claims 2 and 46-55 are under consideration.

Rejections

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 2 stands rejected as set forth in Paper No's 17 (10-25-00) and 20 (5-15-01), and newly presented claims 46-55 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

Applicants argue that their nucleic acids are now isolated or recombinant and thus not naturally occurring. In addition applicants argue that pp. 20-21 discloses biological functions and utilities for IPM molecules as containing hyaluronate-binding motifs, that hyaluronate is a component of IPM and that hyaluronidase disrupts cone matrix sheaths in vitro, weakens retinal adhesion in vivo, that hyaluronate could stabilize the IPM through interactions with CD44, IPM150, IPM200 and other insoluble IPM constituents and that IPM150 could interact with

hyaluronate to effect retinal adhesion. Applicants further teach that the IPM proteins have EGF-like domains known to promote survival of neighboring cells and that IPM is important in maintaining/promoting photoreceptor viability as noted at pp. 19-20.

Applicants arguments filed 11-28-01 have been fully considered but are not persuasive. Applicants comments with respect to IPM molecules in general is not specific to the SEQ ID NO:s of instant claims. In addition, the biological functions of adhesion/stabilization of the interphotoreceptor matrix via interaction with hyaluronate and disruption via hyaluronidase does not appear to be either specific to the relevant nucleic acids or substantiated for IPM molecules in general. Specifically, the peptide sequences claimed have not been demonstrated to bind to hyaluronate, mediate stabilization of the interphotoreceptor matrix or to provide for the effect of retinal adhesion. Thus the prophetic properties of the claimed peptides do not arise to a specific and substantial, credible or well established utility because there is no readily available evidence which would lead the artisan to the reasonable conclusion that such interactions/functions occurred amongst interphotoreceptor matrix proteins either specifically as claimed or generally amongst IPM molecules. The specifications reference to Korte et al., IDS reference AY fails to support the assertion that hyaluronate binds to the instantly claimed sequences or to any particular sequence to mediate stabilization or maintenance of retinal pigment epithelia. It merely suggests hyaluronate localization in the eye and teaches that hyaluronidase treatment was associated with a loss of staining in the retinal pigment epithelia. It is noted that as set forth in IDS reference AN, Hageman and Kuehn teach a vast number of isolated peptides which compose

the interphotoreceptor matrix but fail to evidence or teach any particular peptide interaction suitable to maintain or cause either stabilization or destabilization of the interphotoreceptor matrix. Applicants further suggest that as the sequences of SEQ ID NO's 1, 3 and 5 contain EGF-like domains that the molecules promote survival or the maintenance of photoreceptor viability. Yet no evidence in the specification or supporting literature either specific to SEQ ID NO's: 1, 3 and 5 or generally addressing IPM proteins readily lead the artisan to the conclusion that such properties are provided by the encompassed sequences. In particular, Przysiecki et al., PNAS, Nov. 1987, 84(22):7856-60 note that a variety of functionally diverse proteins exist with EGF-like domains, see in particular abstract, and therefore the artisan could not reasonably presume that the disclosed sequences would likely provide for the promotion, survival or maintenance of photoreceptor viability as asserted. Furthermore, as it was previously noted that the artisan is without knowledge of the significance of the disclosed sequences the artisan would be unable to use the sequence in any particular method as the outcome would be unknown and/or uninterpretable. Thus, as previously set forth the claimed invention lacks utility.

Claim 2 also stands rejected as set forth in Paper No's 17 (10-25-00) and 20 (5-15-01), and newly presented claims 46-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Specifically, since the claimed invention is not supported by either a credible,

specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Status of Claims

10. No claims are allowed.

Conclusion

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
January 25, 2002

Gary L. Kunz
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SUPERVISORY PATENT EXAMINER
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